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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/817,781 | 03/26/2001 | Paul C. Harris | 2065.2001-000 | 7810 |

21005 7590 10/15/2003

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,781

Applicant(s)

HARRIS ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-15 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-15 and 33-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2003 has been entered.
2. Claims 2 and 3 have been canceled. Claims 33-45 have been added. Claims 1, 4-15 and 33-45 are pending.
3. All rejections not reiterated herein below are withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-15 and 33-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuo (EP 0 895 084 A2).

Kuo discloses a method and device for determination of an analyte in a sample of body fluid. The test strip comprises a matrix made of paper, nitrocellulose or nylon material (page 3, lines 43-50). The strip has a first region which contains mobile specific binding partner for the analyte which bears a detectable label such as gold sol or latex particles; a second region

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containing immobilized binding partner which is specific for an epitope of the analyte different than that to which analyte binding gold sol particles are specific; and a third region containing means for capturing the analyte/labeled specific binding partner complex which is not bound in the second region (page 2, line 55 through page 3, line 6). The third region may also contain an immobilized antibody against the labeled binding partner (e.g. anti-mouse IgG when the labeled binding partner is an antibody). See page 4, lines 7-12. Kuo also teaches an absorbent pad which serves to absorb the liquid that migrates past the various zones of the test strip (page 7, lines 56-57). In use, sample is applied to the test strip at an application point, (area 1 of figure 1) and allowed to migrate to the various zones of the test strip. Signals from the detectable label in the second region (sample capture zone) and from the detectable label in the third region (control capture zone) are measured and the ratios of these signals is determined and related to the amount of the analyte in the sample. Kuo teaches that such a determination provides the advantage of an increase in accuracies, because it corrects for inaccuracies in labeled conjugate deposition and/or non-uniform flow through the matrix (page 4, lines 6-17). Kuo also teaches a method in which the summation of the signal from both the sample capture and control capture zones is taken, and the ratio of the signal in the sample capture zone and the sum is used to determine the amount of analyte (page 4, lines 34-37). Kuo teaches that the test strip and method disclosed may be adapted to determine various types of analytes such as PSA and hCG (page 7, lines 13-21) in body samples such as serum.

Response to Arguments

6. Applicant's arguments filed 4/15/03 have been fully considered but they are not persuasive.

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7. Applicant argues that Kuo teaches that the second zone contains immobilized analyte and that the present invention does not contemplate using immobilized analyte. This argument has been fully considered, however, in addition to the use of immobilized analyte, Kuo specifically teaches an embodiment where a binding partner which is specific for an epitope of the analyte different than that to which the labeled binding partner is specific is used (page 3, lines 1-2). In this embodiment, this binding partner is the same as those of the instant invention.

Applicant argues that in a second embodiment of Kuo, the second zone contains antibody to the analyte, and the third zone has more antibody to the analyte. The binding at both regions would be of the analyte and that Kuo teaches that a ratio is generated from the signal in these two regions, and because both capture antibodies are specific for the analyte, it cannot correct for intrinsic assay variability.

These arguments have been fully considered but are not deemed to be persuasive. Kuo specifically teaches a second zone containing immobilized binding partner for the analyte and a third zone containing means for capturing the analyte/^(sample capture)labeled specific binding partner complex which is not bound in the second zone. Kuo teaches at page 4, lines 6-12, an immobilized antibody against the labeled binding partner (e.g. anti-mouse IgG when the labeled binding partner is an antibody) is the capture means. Therefore, Kuo teaches binding partners that have the same binding capabilities as those of the instant invention.

Applicant argues that Kuo teaches the use of separate marker in a fourth zone to correct for the sample concentration and that such a zone is not used in the instant invention. This argument is not persuasive because Kuo teaches the invention as claimed. The fact that it discloses additional structure and/or step not claimed is irrelevant. Kuo teaches raising the signals from the labeled binding partner immobilized in the second region and the labeled

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binding partner captured in the third region and determining the concentration of the analyte by comparing to known concentration of analytes determined using the same method. See page 3, lines 19-29. Kuo further teaches the summation of the signal from the second and third zones and using this summation to determine a ratio. See page 4, lines 34-37.


In conclusion, Kuo teaches every aspect of the claimed invention and anticipates the claims.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. – 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Primary Examiner
23 July 2003